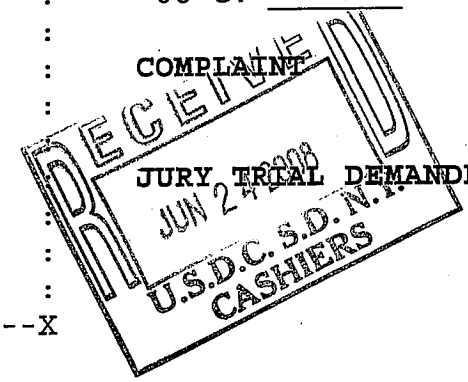
08 CV 5665

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

MARGARET CUMMING, Plaintiff, v. PROCTER & GAMBLE PHARMACEUTICALS, INC. and AVENTIS PHARMACEUTICALS, INC., Defendants.	Civil Action No. 08 CV _____ **COMPLAINT** **JURY TRIAL DEMANDED**



Plaintiff Margaret Cumming ("Plaintiff"), by her attorneys, for her Complaint against Procter & Gamble Pharmaceuticals, Inc. ("P&GP") and Aventis Pharmaceuticals, Inc. ("Aventis") (also, collectively, "defendants"), alleges:

1. This is a civil action for damages suffered by Plaintiff as a result of her being prescribed and ingesting Defendants' drug Actonel.

PARTIES

2. Plaintiff is a citizen and resident of the Country of Australia, residing in Victoria, Australia.

3. At all times herein mentioned, Defendant P&GP was and is a Ohio corporation, with its principal place of business at One Proctor Gamble Plaza, Cincinnati, Ohio 45202-3393.

4. At all times herein mentioned, Defendant Aventis was and is a Delaware corporation, with its principal place of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

5. At all times herein mentioned, Defendants did business in the States of New York and Victoria, Australia 1020.

JURISDICTION

6. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars ($75,000.00) and Plaintiff is a citizen of a State which is different from the State where defendants are incorporated and have their principal places of business.

FACTUAL BACKGROUND

7. Defendants designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

8. Actonel is the brand name of risedronate sodium, which is in a class of prescription drugs called bisphosphonates. Actonel is taken orally.

9. Actonel was approved by the United States Food and Drug Administration for treatment of osteoporosis.

10. The product literature prepared by defendants and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

11. In 2002 or before, Defendants knew or should have known that a physician reported that several of his patients who were given Aredia, another bisphosphonate, were diagnosed with osteonecrosis of the jaw and that the physician believed a causal relationship existed between the use of bisphosphonates and osteonecrosis of the jaw.

12. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa, also a bisphosphonate. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

13. In September 2004 and May 2005, another manufacturer sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of its bisphosphonates, Aredia and Zometa.

14. Defendants never issued any warnings or changed their product literature to warn of the risk of osteonecrosis of the jaw.

15. Plaintiff was prescribed and took Actonel.

16. As a result of taking Actonel, Plaintiff developed osteonecrosis of the jaw.

17. As a result of taking Actonel Plaintiff suffered compensable injuries, including but not limited to the following:

a. severe and permanent physical and medical injuries and associated disabilities;

b. severe past and future pain and suffering;

c. severe past and future mental anguish;

d. loss of enjoyment of life;

e. increased risk of health problems;

f. past and future medical care and monitoring; and

g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

18. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 17 of the Complaint as if they were set forth here in full.

19. Defendants designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

20. Actonel as designed, manufactured and sold by Defendants was defective in design or formulation in that it was unreasonably dangerous.

21. Actonel as designed, manufactured and sold by Defendants was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

22. Actonel as designed, manufactured and sold by Defendants was defective due to inadequate warnings because Defendants knew or should have known that the product created a risk of harm to consumers.

23. Actonel as designed, manufactured and sold by Defendants was defective due to inadequate testing.

24. As the proximate cause and result of the defective condition of Actonel as designed, manufactured and sold by Defendants, Plaintiff was injured.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure To Warn]

25. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 17 of the Complaint as if they were set forth here in full.

26. Defendants designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

27. Actonel as designed, manufactured and sold by Defendants was not accompanied by proper warnings regarding possible adverse side effects.

28. Defendants knew or should have known about the possible adverse side effects of Actonel, including osteonecrosis of the jaw.

29. As the proximate cause and result of Defendants' failure to properly warn physicians and consumers, Plaintiff was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

30. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 17 of the Complaint as if they were set forth here in full.

31. Defendants designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel.

32. Defendants had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel, including a duty to assure that users, like Plaintiff, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

33. Defendants failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel in that Defendants knew or should have known that Actonel created an unreasonable risk of osteonecrosis of the jaw.

34. Defendants were negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Actonel.

35. As the proximate cause and result of Defendants' negligence, Plaintiff was injured.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

36. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 17 of the Complaint as if they were set forth here in full.

37. Defendants expressly warranted, by and through statements made by Defendants or their authorized agents, that Actonel was safe, effective, and fit for its intended use.

38. Plaintiff, and her agents, relied on the skill, judgment and representations of Defendants.

39. Actonel did not conform to Defendants' express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

40. As the proximate cause and result of Defendants' breach of their express warranties, Plaintiff was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

41. Plaintiff incorporates by reference the allegations contained in Paragraphs 1 through 17 of the Complaint as if they were set forth here in full.

42. Defendants impliedly warranted to Plaintiff, and her agents, that Actonel was of merchantable quality and was safe and fit for its intended use.

43. Plaintiff, and her agents, relied on Defendants' skill and judgment.

44. Actonel was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

45. As the proximate cause and result of Defendants' breach of its implied warranties, Plaintiff was injured.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Margaret Cumming respectfully prays for relief and judgment against the defendants as follows:

(a) compensatory damages in an amount to be determined at trial;

(b) attorneys' fees, expenses, and costs of this action; and

(c) for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York
June 23, 2008

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